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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,700	05/22/2001	Takao Nakagawa	KAW-75	9733
24956	7590	02/05/2004	EXAMINER	
MATTINGLY, STANGER & MALUR, P.C. 1800 DIAGONAL ROAD SUITE 370 ALEXANDRIA, VA 22314			GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/862,700	Applicant(s) NAKAGAWA ET AL.	
	Examiner Brian R. Gordon	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-7-03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on November 24, 2000. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b).

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites: "a sample pick up step in which said sample is caught and held on the tip of the sampling needle and moved away from the surface on which the sample **is attached** by using a sampling apparatus in which a said moving member, is adjustable so as to be reciprocatably movable between a waiting position where the position of the tip of the sampling needle is spaced from the focus position of the object

lens and a sampling position where the tip of the sampling needle is situated at the focus position of the object lens whereby said sample may be analyzed."

It is unclear if the sample still remains on the surface or if the sample is totally removed by the needle.

It appears as if the phrase "is attached" should read "was located" to imply that the sample located on the surface has been removed. If applicant intent is to imply that only a portion of the sample located on the surface is caught on the tip and moved, then the claim should clearly state this intent. As presently interpreted for the purpose of examination the entire sample is caught on the tip and moved.

Response to Arguments

Claim 1 claims elements such as a fixed frame, moving member, and others in form structurally relative to an object lens and an optical microscope. It appears that applicant's invention is actually a device that is intended to be used in conjunction with an optical microscope. It is suggested that applicant positively claim the optical microscope and the objective lens are both required elements of the invention. Since the microscope and objective lens are not positively claimed as elements of the invention. The claims are addressed as broadly interpreted. Therefore, the optical microscope and object lens are provided to express intended use.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

On page 24 of applicant's remarks applicant states, "The present invention relates to a sampling apparatus and, as defined in amended claim 1, comprises a frame

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fixed to an object lens of an optical microscope"; however, claim 1 specifically claims "a frame fixed at a prescribed position relative to an object lens of an optical microscope". There is a difference in what is said in the remarks and what is presented in the claims. The term of being **fixed at a prescribed position relative to an object lens** is not the same as **being fixed to an object lens**.

Claim 1 does not require that the frame be fixed to an object lens. It only requires that the frame be fixed (not move) relative to an object lens. As such the argument is not commensurate in scope with that of the claims.

Applicant's arguments on page 24 last paragraph through page 26 are directed to the method of claim. Fowler has not been applied to reject the limitations of claim 4. The arguments as directed to the claim 4 in relationship to the limitations of claim 1 are considered intended use. Applicant states that the device of Fowler is not directed to the function of moving a sample. The examiner asserts that while Fowler may not specifically recite that the device is employed to move the sample, the device is structurally equivalent and may be used to move a sample as intended by applicant.

On page 26, applicant asserts Fowler lacks a moving member and moveable needle. As previously stated in the 102 rejection "To achieve these vertical and horizontal distances, **the ring adapter 40 can be adjusted up and down** the barrel of the microscope objective 42, as indicated, and the **needle-like tube 58 can be adjusted up and down the angled groove 64 through hole 66**, also as indicated. These adjustments are made by simply loosening and retightening the mounting screw 74 and the locking screw 68 after the ring adapter 40 and the electronic marker assembly 22 have been repositioned, respectively." As indicated in the passage both the ring adapter and needle are moveable to be adjusted to desired positions.

Applicant does admit that the elements are adjustable (on page 27), but asserts that they are not reciprocable. As stated above both elements are moved up and down.

Applicant attempts to distinguish the invention of the instant claims and that of Syska et al. by addressing the amplitude of vibration of tips, the sample size collected by the device, and the number of shafts required. All of these issues are not mentioned in any of the claims, hence they are not commensurate in scope with that of the claims. Furthermore applicant argues that the frame is fixed to an object lens of a microscope. As previously stated above the claims do not state that the frame is attached or fixed to an object lens of a microscope. As such the argument is not commensurate in scope with that of the claim.

As to the parts of the frame, member, and means not being shown or taught by Syska et al., the examiner asserts Figure 1 clearly shows a frame supporting holders that are coupled to drive means.

Applicant attempts to distinguish the invention of the instant claims and that of Miyoshi by addressing vibration of the probe, the stiffness level of the probe, and the geometrical shape of the element supporting the probe. All of these issues are not mentioned in any of the claims; hence they are not commensurate in scope with that of the claims.

Contrary to applicant's assertions, the examiner asserts Miyoshi provides for structural equivalence of the moving member and holding device 17 of the instant claims in the passage provided: "The micromanipulator 4 comprises a rod- or needle-

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shaped manipulation probe 6 and a transfer control device 8 (moving member), which can move the probe 6 in a given direction and locate it in a given position. The manipulation probe 6 is supported (holder) on the control device 8 by means of a mounting holder 10. The micromanipulator 4 is attached to a microscope body 14 by means of a manipulator fixing member 12.

According to this micromanipulator 4, the manipulation probe 6 is operated (sampling method) for a sample (e.g., cell, fertilized egg, etc.) 20 in a vessel 18 that is placed on a microscope stage 16. By doing this, the sample 20 is situated in the view range of an objective lens 22, or the sample 20 in the view range of the lens 22 is reoriented.

For reasons given herein, the previous art rejections are hereby maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fowler et al. US 5,574,594.

Fowler et al. discloses an automated microscope slide marking device 10 for making reference marks on the surface of microscope slides.

FIG. 1, shows an arrangement of the component parts of the present invention automated microscope slide marking device 10. Included in this arrangement is a switching module 12 having a push-button 14 and three separate electrical sockets 16,18,20, an electronic marker assembly 22 having a support 24, an electrical actuator 26 secured to the support 24, a **needle** marker cartridge 28 also secured to the support 24, and an electrical plug 30 for making an electrical connection between the electrical actuator 26 to the first 16 of the electrical sockets of the switching module 12, a foot-switch 32 having an electrical plug 34 for making an electrical connection to the second 18 of the electrical sockets of the switching module 12, an AC to DC wall plug voltage transformer 36 having an electrical plug 38 for making an electrical connection to the third 20 of the electrical sockets of the switching module 12, and a ring adapter 40 which is designed to **fit around the barrel of a microscope objective 42** and to secure the electronic marker assembly 22 thereto.

The solenoid coil of the electrical actuator 26 is energized when either the push-button 14 or the foot-switch 32 is engaged by the microscope user. Thus, the switching module 12 performs an ORing function (elastic member affect) between the push-button 14 and the foot-switch 32. The AC to DC wall plug voltage transformer 36 supplies the switching module 12 with a DC operating voltage. The operating voltage, typically 12 or 24 volts, allows the switching module to perform the ORing function and to energize the solenoid coil of the electrical actuator 26. The push-button 14 and the foot-switch 32 are

provided to give the microscope user an option of placing, and then engaging, either at an ergonomically desirable position.

Referring to FIG. 9, the electronic marker assembly 22 is shown being directed into the angled groove 64 of the ring adapter 40, with the needle-like tube 58 being directed into hole 66. Once the electronic marker assembly 22 is positioned within the angled groove 64, it is secured by tightening the locking thumbscrew 68 against the needle-like tube 58. Referring to FIG. 10, the electronic marker assembly 22 is shown secured to the ring adapter 40, while the ring adapter 40 is being fit around the barrel of the microscope objective 42. Once the ring adapter 40 is positioned around the barrel of the microscope objective 42, it is secured in place by tightening the mounting screws 74 (which also allows it to be detached) against the barrel 42.

The ideal position of the needle-like tube 58 with respect to the slide 90 is such that there should be approximately 1.5 mm of vertical clearance therebetween when the image viewed through the microscope is brought into focus. Furthermore, the needle-like tube 58 should not appear in the field of view, but the reference mark that is made by the plastic fiber 62 should appear at the edge of the field of view. When using an E Plan LWD 10X power microscope objective or other objectives, such can be accomplished by horizontally positioning the needle-like tube 58 approximately 1.25 mm from the center of the field of view. To achieve these vertical and horizontal distances, the ring adapter 40 can be adjusted up and down the barrel of the microscope objective 42, as indicated, and the needle-like tube 58 can be adjusted up and down the angled groove 64 through hole 66, also as indicated. These adjustments are made by simply

loosening and retightening the mounting screw 74 and the locking screw 68 after the ring adapter 40 and the electronic marker assembly 22 have been repositioned, respectively. It should be noted that the needle-like tube 58 may be bent slightly, as shown, to make minor positioning adjustments.

7. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Syska et al. US 6,159,199.

Syska et al. disclose a device for handling instruments used in technical cytological examinations has a holder base with at least two separate and moveable holders each carrying one instrument and each being coupled with a drive for switching the holders between two defined positions, one of which is a working position and the other is a rest position. In the working position, the distal end of the instrument located in the holder is aligned during a technical cytological intervention in the region of cellular material which is to be treated. In the rest position, the instrument held in the holder is kept at a safe distance from the cellular material which is to be treated. The drives are coupled with each other so that, when activated, they switch the holders between their rest and working position, respectively.

Generally, such devices are thus equipped, for example, with a holder base which provides a separate, moveable holder for each instrument. Each of the holders is coupled to a drive which can shift it from a resting to a working position. Before beginning an intervention, the holder base which is outfitted with the instruments is macroscopically pre-adjusted, and then each of its holders is precisely adjusted by means of set screws, for example, until in the working position the free ends of the

instruments mounted in the holders are mapped into the field of vision of the microscope. In this way it is made certain that--while a specific holder is being shifted into the working position--the free end of the instrument held in the selected holder is automatically placed into the operator's field of vision and thereby in direct proximity to the cellular material to be treated, and that it does not have to be re-adjusted by the operator each time in a time-consuming process.

The invention provides that drives controlling the holders are so coupled together that when they are activated at least two of the holders are shifted into the working and resting positions, respectively. Consequently, in accordance with the invention the operator can bring about a carefully aimed exchange of positions between the positions of both hollow needles by means of an activation (hence in a single operator step), if during an intervention the above referenced etching capillary tube is located in the working position and the biopsy capillary is in the resting position.

FIG. 1 schematically shows a Petrie dish 20 in which has been placed a sample of cellular material 21. Ordinarily, and as shown, sample 21 is enclosed in a drop of culture medium 22 and totally surrounded by a layer of oil 23.

A microscope table 24 on which the Petrie dish 20 rests and a lens 25 of a microscope which is needed for optical inspection of the technical cytological intervention are schematically shown. In the illustrated example, hollow needle 12b of instrument 12 is so positioned by holder 14 that its free end is located as close as possible in direct proximity to cell sample 21 in culture medium 22. In any event, hollow needle 12b of instrument 12 is located in the precisely mapped field of vision of lens 25.

Instrument 11, on the other hand, is positioned by the holder which is not shown in the figure into the resting position in which the free end of hollow needle 11b is located at a distance above cell sample 21, but still dipping into the oil pool or film 23. The positions which are illustrated represent ideal positions. Differently selected set-ups are also conceivable, of course, within limits.

While Syska teaches that the device is for dispensing, it is inherent that the device could also be used to collect or withdraw material from the sampling location.

8. Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyoshi US 6,411,433.

Miyoshi discloses a micromanipulator having a high-stiffness manipulation probe capable of carrying out a manipulation process in the view range of a microscope without modifying an existing observation optical system. The micromanipulator comprises a manipulation probe protruding from a probe supporting member, which is connectedly supported on a transfer control device by means of a hold member. The manipulation probe can be moved (e.g., translated or rotated) for a desired stroke in a desired direction by driving the transfer control device to move the probe supporting member finely.

The micromanipulator 4 comprises a rod- or needle-shaped manipulation probe 6 and a transfer control device 8, which can move the probe 6 in a given direction and locate it in a given position. The manipulation probe 6 is supported on the control device 8 by means of a mounting holder 10. The micromanipulator 4 is attached to a microscope body 14 by means of a manipulator fixing member 12.

According to this micromanipulator 4, the manipulation probe 6 is operated for a sample (e.g., cell, fertilized egg, etc.) 20 in a vessel 18 that is placed on a microscope stage 16. By doing this, the sample 20 is situated in the view range of an objective lens 22, or the sample 20 in the view range of the lens 22 is reoriented.

Supposedly, the manipulation probe 6 of the first prior art may be positioned with respect to the sample 20 that adheres to the inside of a transparent frame 24, as shown in FIG. 12, for example, or the probe 6 may be inserted into the view range of the high-magnification objective lens 22 whose working distance is short. Usually, therefore, the distal end of the manipulation probe 6 is sharp and elongated so that the probe 6 can be inserted securely and smoothly into the narrow working space.

Illumination light from a condenser lens 28 opposed to a transparent plate 26 that constitutes the frame 24, for example, is applied to the sample 20 and the manipulation probe 6 in the working space with the probe 6 in the frame 24. By doing this, the sample 20 and the manipulation probe 6 can be observed microscopically as the sample 20 is manipulated by means of the probe 6.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
January 20, 2004


Jill Warden
Supervisory Patent Examiner
Technology Center 1700